Roche

Diagnostics

EC- Declaration of Conformity

According to Annex III of the Directive 98/79/EC of the European Parliament and of the Council of 27. October 1998

Manufacturer:

Hitachi High-Technologies Corporation
1-24-14 Nishi-Shinbashi
Minato-ku, Tokyo 105-8717, Japan

Authorised Representative:

Roche Diagnostics GmbH
Sandhofer Straße 116
D-68305 Mannheim, Germany

Roche Diagnostics GmbH declares that the in vitro diagnostic medical instrument

Product name: Modular Analytics SWA
Configuration designation: Modular-XYZ GS

- number of E-modules: 0-6
- number of P-modules: 0-4
- number of D-modules: 0-4

Description: Integrated system for clinical and immunological tests, intended for in-vitro determination of a wide range of analytes

relating to this declaration, complies with the requirements of EC Directive 98/79/EC of the Council of October 27, 1998 concerning in-vitro diagnostic medical devices.

Mannheim, July 16, 2002

Roche Diagnostics GmbH

Dr. M. Thein
Head of Quality Management
Centralized Diagnostics

Dr. M. Hahn
Head of Quality Management
Roche Instrument Center AG

Contact address:

Roche Diagnostics GmbH
Regulatory Affairs
Sandhofer Straße 116
D-68305 Mannheim, Germany
Fax: **49 621 759 1448